

1 **Claims**

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3 1. A method of monitoring the progression of
4 diabetes from a first timepoint to a later
5 timepoint, said method comprising the steps
6 providing a first biological sample
7 obtained at the first timepoint,
8 measuring the concentration of glycated
9 insulin in said biological sample,
10 providing a second biological sample
11 obtained at the later timepoint,
12 measuring the concentration of glycated
13 insulin in said second biological sample,
14 determining the difference in
15 concentration of glycated insulin between
16 the first and second biological samples,
17 wherein a lower concentration at the
18 second timepoint is indicative of
19 increased disease severity and/or loss of
20 control of blood glucose.

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22 2. A method of early diagnosis of diabetes in an
23 individual, the method comprising the steps
24 providing a biological sample in which glucose
25 levels are within a normal range from said
26 individual,
27 measuring the concentration of glycated insulin
28 in the biological sample,
29 wherein the presence of glycated insulin at a
30 concentration greater than a predetermined minimum
31 is indicative of the presence of diabetes.

32

- 1 3. A method of predicting the onset of diabetes in
2 an individual, the method including the steps
3 of;
4 providing a biological sample from said
5 individual,
6 measuring the concentration of glycated insulin
7 in the biological sample,
8 wherein the presence of glycated insulin at a
9 concentration greater than a predetermined
10 minimum is indicative of predisposition to
11 diabetes.
12
- 13 4. The method according to claim 3, wherein the
14 concentration of glucose in the biological
15 sample is within the normal range.
16
- 17 5. The method according to claim 2 or claim 4
18 wherein the normal range of glucose is less than
19 11.1 mmol/l in a random plasma sample.
20
- 21 6. The method according to any one of claims 2 to 5
22 wherein said predetermined minimum concentration
23 is the concentration of glycated insulin
24 measured in a sample from the same individual at
25 an earlier timepoint.
26
- 27 7. The method according to any one of claims 2 to
28 6, wherein said predetermined minimum
29 concentration of glycated insulin in a non
30 fasted sample is at least 20 pmol/l.
31

- 1 8. A method as claimed in any preceding claim
2 wherein glycated insulin in the sample is
3 measured by means of radioimmunoassay (RIA).
4
- 5 9. Use of glycated insulin, as a predictive marker
6 for glucose intolerance and/or diabetes.
7
- 8 10. Use of glycated insulin as a predictive marker
9 for prediabetes or to predict the onset of
10 diabetes.
11
- 12 11. An *in vitro* assay method for detecting diabetes
13 or the predisposition to diabetes by determining
14 the presence of glycated insulin in a biological
15 sample, in which glucose levels are normal, said
16 assay method comprising the steps:
17 providing a biological sample;
18 determining whether the concentration of
19 glycated insulin in the biological sample is at
20 least 20 pmol/l;
21 wherein the presence of glycated insulin at a
22 concentration greater than 20 pmol/l is
23 indicative of diabetes or predisposition to
24 diabetes.
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